IN THE UNITED STATES PATENT AND TRADEMARK OFFICE e Application of: West et al.

Art Unit: 1615

Examiner: Di Nola Baron, Liliana

Filed: September 1, 2000

For: Nitric Oxide-Producing Hydrogel

**Materials** 

Serial No. 09/653,406

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

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Respectfully submitted,

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Our Docket:

47400-0100 (47400-252658)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on January 5, 2004.

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Application Number 09/653,406					
Filing Date 09/01/2000					
First Named Inventor Jennifer L. West					
Group Art Unit 1615					
Examiner Name Di Nola Baron, Liliana					
Attorney Docket Number	47400-0100 (47400-252658)				

U.S. Patent Docum			Document Kind Code <sup>2</sup>		Date of Publication of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant
Examiner Initials	Cite No.1	Number	(if known)	of Cited Document	MM-DD-YYYY	Figures Appear
	1	4,526,938		Churchill et al.	07-02-1985	
	2	4,716,203		Casey et al.	12-29-1987	
	3	4,741,337		Smith et al.	05-03-1988	
	4	4,957,744		della Valle et al.	09-18-1990	
	5	4,987,744		Handley et al.	01-29-1991	
	6	5,410,016		Hubbell et al.	04-25-1995	
	7	5,508,317		Müller	04-16-1996	
	8	5,632,981		Saavedra et al.	05-27-1997	
	9	5,665,840		Pöhlmann et al.	09-09-1997	
	10	5,807,927		Stockinger et al.	09-15-1998	
- <del></del>	11	5,849,839		Hubbell et al.	12-15-1998	
	12	5,849,841		Mühlebach et al.	12-15-1998	
	13	5,900,433		Igo et al.	05-04-1999	
	14	5,910,316		Keefer et al.	06-08-1999	
	15	5,932,674		Müller	08-03-1999	
	16	5,939,489		Müller	08-17-1999	
-,	17	6,011,077		Müller	01-04-2000	
	18	6,299,604	B1	Ragheb et al.	10-09-2001	
	19	6,262,206		Nesvadba et al.	07-17-2001	

· -			Foreign Patent Document		Date of Publication of	Pages, Columns, Lines,	
Examiner Initials	Cite No. <sup>1</sup>	Office <sup>3</sup>	Kind Code <sup>4</sup> Number <sup>4</sup> (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear	Т
•	20	PCT	WO 96/32136	The United States of Americaet al.	10-17-1996		
	21	PCT	WO96/15797	The United States of America represented by the Secretary, Dept. of Health and Human Services	05-30-1996		
	22	PCT	WO 01/15738	Rice University	03-08-2001		
							1

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Complete if Known					
Application Numb r 09/653,406					
Filing Date	09/01/2000				
First Named Inventor Jennifer L. West					
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Attorney Docket Number	47400-0100 (47400-252658)				

		OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS	<del></del>
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	23	BOHL et al., "Nitric oxide-generating polymers reduce platelet adhesion and smooth muscle cell proliferation", Biomaterials,	
		2000, 2273-2278, Vol. 21	
	24	BOHL et al., "Nitric Oxide-Releasing Materials for the Prevention of Thrombosis and Restenosis", Proceed. Int'l. Sym. Control.	
		Rel. Bioact. Mater., 2000, 143-144, Vol. 27	
<u></u>	25	BOHL et al., "Nitric Oxide Producing Materials: A Potential Therapy for Thrombosis and Restenosis", Proceed. Int'l. Sym.	
		Control. Rel. Bioact. Mater., 1999, 56-57, Vol. 26	
<u></u>	26	BOHL et al., "Nitric Oxide-Releasing Hydrogels for the Prevention of Thrombosis and Restenosis", Circulation, Oct. 31, 2000;	
		II.734, Vol. 102, No. 18 (Abstract only)	
	27	COHN et al, "Biodegradable PEO/PLA block polymers", J. Biomed. Mater. Res., 1988, 993-1009, Vol. 22	
	28	COOKE et al., "Antiatherogenic Effects of L-Arginine in the Hypercholesterolemic Rabbit", J. Clin. Invest., 1992, 1168-1172,	
•		Vol. 90	
	29	DE GRAAF et al., "Nitric Oxide Functions as an Inhibitor of Platelet Adhesion Under Flow Conditions", Circulation, 1992, 2284-	
-		2290, Vol. 85	
	30	DE MEYER et al., "Effect of Nitric Oxide Donors on Neointima Formation and Vascular Reactivity in the Collared Carotid Artery	
		of Rabbits", J. Cardiovasc. Res., 1995, 272-279, Vol. 26	
	31	DIODATI et al., "Complexes of Nitric Oxide with Nucleophiles as Agents for the Controlled Biological Release of Nitric Oxide:	
		Hemodynamic Effect in the Rabbit", J. Cardiovasc. Pharm., 1993, 287-292, Vol. 22	
	32	DIODATI et al., "Complexes of Nitric Oxide with Nucleophiles as Agents for the Controlled Biological Release of Nitric Oxide:	
		Antiplatelet Effect", Throm. Haem., 1993, 654-658, 1993	
	33	GARG et al., "Nitric Oxide-Generating Vasodilators and 8-Bromo Cyclic Guanosine Monophosphate Inhibit Mitogenesis and	
		Proliferation of Cultured Rat Vascular Smooth Muscle Cells", J. Clin. Invest., 1989, 1774-1777, Vol. 83	
	34	GREENHALGH, "The Role of Growth Factors in Wound Healing", J. Trauma, 1996, 159-167, Vol. 41	
	35	HELLER et al., "Nitric Oxide Inhibits Proliferation of Human Endothelial Cells via a Mechanism Independent of cGMP",	
		Atherosclerosis, 1999, 49-57, Vol. 144	
<u>.                                      </u>	36	HERN et al., "Incorporation of Adhesion Peptides into Nonadhesive Hydrogels Useful for Tissue Resurfacing", J. Biomed.	$\vdash$
		Mater. Res., 1998, 266-276, Vol. 39	

Examiner	Date Considered	RECEIVED
Signature	Considered	

<sup>&</sup>lt;sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language translation is attached.

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Complete if Known **Application Number** 09/653,406 **Filing Date** 09/01/2000 **First Named Inventor** Jennifer L. West Group Art Unit 1615 **Examiner Name** Di Nola Baron, Liliana

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	<del></del>	OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS  Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the	
Examiner Initials	Cite No. <sup>1</sup>	item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s),  publisher, city and/or country where published	T <sup>*</sup>
	37	HOLLAND et al., "Polymers for Biodegradable Medical Devices. 1. The Potential of Polyesters as Controlled Macromolecular	
		Release Systems, 1986, 155-180, Vol. 4	
	38	IGNARRO et al., "Mechanism of Vascular Smooth Muscle Relaxation by Organic Nitrates, Nitrites, Nitroprusside and Nitric	
		Oxide: Evidence for the Involvement of S-Nitrosothiols as Active Intermediates", J. Pharmacol. Exp. Ther., 1981, 739-749, Vol.	
		218	
	39	KWON et al., "Inhibition of Tumor Cell Ribonucleotide Reductase by Macrophage-derived Nitric Oxide", J. Exp. Med., 1991,	
		761-767, Vol. 174	
	40	LEFER et al., "Antineutrophil and Myocardial Protecting Actions of a Novel Nitric Oxide Donor After Acute Myocardial Ischemia	
u.		and Reperfusion in Dogs", Circulation, 1993, 2337-2350, Vol. 88	
	41	LEGRAND et al., "Preclinical Promise of Becaplermin (rhPDGF-BB) in Wound Healing", Am. J. Surg., 1998, 48S-54S, Vol 176	
•	42	LEPOIVRE et al., "Inactivation of Ribonucleotide Reductase by Nitric Oxide", Biochem. Biophys. Res. Comm., 1991, 442-448,	
		Vol. 179	
	43	MANN et al., "Tethered-TGF-β Increases Extracellular Matrix Production of Vascular Smooth Muscle Cells", Biomaterials,	
		2001, 439-444, Vol. 22	
	44	MARAGOS et al., "Nitric Oxide/Nucleophile Complexes Inhibit the in Vitro Proliferation of A375 Melanoma Cells via Nitric	
		Oxide Release", Cancer Res., 1993, 564-568, Vol. 53	
	45	MARTINEZ-DE JESUS et al., "Randomized Single-Blind Trial of Topical Ketanserin for Healing Acceleration of Diabetic Foot	
		Ulcers", Arch. Med. Res., 1997, 95-99, Vol. Spring 28 (1) (Abstract only)	
	46	MATHEWS et al., "Biological Activity of S-Nitrosothiols: The Role of Nitric Oxide", J. Pharmacol. Exp. Therap., 1993, 1529-	
		1537, Vol. 267	
	47	MORO et al., "cGMP Mediates the Vascular and Platelet Actions of Nitric Oxide: Confirmation Using an Inhibitor of the Soluble	
		Guanylyl Cyclase", Proc. Natl. Acad. Sci. USA, 1996, 1480-1485, Vol. 93	
	48	RODOMSKI et al., "Comparative Pharmacology of Endothelium-Derived Relaxing Factor, Nitric Oxide and Prostacyclin in	
		Platelets", Br. J. Pharmacol., 1987, 181-187, Vol. 92	
<del></del>	49	SARKAR et al., "Nitric Oxide Inhibition of Endothelial Cell Mitogenesis and Proliferation", Surgery, 1995, 274-279, Vol. 118	

Examiner Signature		Date Considered	RECEIVED
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<sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language translation is attached.

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		(use as many sheets as necessary	Examiner Name	Di Nola Baron, Liliana		
Sheet	4	of 4	Attorney Docket Number	47400-0100 (47400-252658)		
		OTHER INFORMATION - NON P	DATENT LITEDATURE DOCUME	NTS		
	50	SAWHNEY et al., "Rapidly Degraded Terpolymers of d	Il-Lactide, Glycolide, and ε-Caprol	actone with Increased Hydrophilicity		
		by Copolymerization with Polyethers", J. Biomed. Res.	, 1990, 1397-1411, Vol. 24			
	51	SCOTT-BURDEN et al., "Extracellular Matrix: Different	ial Influence on Growth and Biosy	In thesis Patterns of Vascular Smooth		
		Muscle Cells from SHR and WKY Rats", J. Cell Physio	I., 1989, 267-274, Vol. 141			
	52	SCOTT-BURDEN et al., "Genetically Engineered Smoo	oth Muscle Cells as Linings to Im	prove the Biocompatibility of		
		Cardiovascular Prostheses", Circulation, 1996, Il235-23	38, Vol. 94 (9 Suppl.)			
	53	SMITH et al., "Nitric Oxide-Releasing Polymers Contain	ning the [N(O)NO] Group", J. Me	d. Chem., 1996, 1148-1156, Vol. 39		
	54	SPILIZEWSKI et al., "The Effect of Hydrocortisone Ace	etate Loaded Poly (DL-Lactide) Fi	lms on the Inflammatory Response", J.		
		Control. Rel., 1985, 197-203, Vol. 2				
<u>r,</u>	55	STUEHR et al., "Nitric Oxide – A Macrophage Product	Responsible for Cytostasis and F	Respiratory Inhibition in Tumor Target		
		Cells", J. Exp. Med., 1989, 1543-1555, Vol. 169				
	56	WILLIAMS et al., 'Safety and Tolerability of Intravenous	s-to-Oral Treatment and Single-D	lose Intravenous or Oral Prophylaxis		
		with Trovafloxacin", Am. J. Surg., 1998, 74S-79S, Vol.				
	57	WIEMAN et al., ,"Efficacy and Safety of a Topical Gel I	Formulation of Recombinant Hum	an Platelet-Derived Growth Factor-BB		
		(Becaplermin) in Patients with Chronic Neuropathic Dia	abetic Ulcers", Diabetes Care, 19	98, 822-827, Vol. 21		
	58	ZICHE et al., "Nitric Oxide Promotes DNA Synthesis ar	nd Cyclic GMP Formation in Endo	othelial Cells from Postcapillary		
		Venules", Biochem. Biophys. Res. Comm., 1993, 1198	3-1203, Vol. 192			
	59	Abstract, Derwent WPI, HU 9801673 A1 (08-28-2000),	(Cycl-N) Cyclolab Ciklodextrin K	utato Fejleszto,		

	 , <del></del>	· · · · · · · · · · · · · · · · · · ·
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